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EXAMINER	
ROGERS, KRISTIN D	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,108	ROSENBERG, MEIR	
	Examiner	Art Unit	
	Kristin D. Rogers	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *34 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-33, drawn to a pressure sensor device and method of use, classified in class 600, subclass 561.

   II. Claims 34-35, drawn to a method of manufacturing a pressure sensor device, classified in class 427, subclass 2.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as heat shrinking a material over the opening in the sidewall of the catheter.

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Lisa J. Michaud on January 11, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-33. Affirmation of this election must be made by applicant in replying to this

Office action. Claims 34 and 35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. The Examiner acknowledges the Applicant's election of Group I drawn to Claims 1-33 for examination in this first action.

Drawings

6. The drawings were received on February 28, 2005. These drawings are acceptable.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 9-10, 21-23, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Bobo, Sr. (5573007). In regard to claim 1, Bobo, Sr. shows a pressure monitoring catheter having an elongate catheter 12d, first lumen 50, second lumen 22 which is separate and fluid-filled, second lumen extending between a pressure-sensitive component 26, and a pressure sensor 14 (Figure 6b). In regard to claim 2, Bobo, Sr. shows an elongate catheter including a sidewall 20 extending between the proximal and distal ends and a first lumen 50 with a fluid entry port 52 formed in the sidewall 20 and adjacent to the distal end. In regard to claim 3, Bobo, Sr. shows a pressure sensitive component 26 at the distal end of the second lumen 22 and the pressure sensor 14

coupled to the proximal end of the catheter. In regard to claim 4, Bobo, Sr. shows a pressure sensitive component 26 including a first surface 28 in contact with fluid of the second lumen 22 with an opposed surface exposed to an external pressure source. In regard to claim 5, Bobo, Sr. shows a pressure sensitive component 26 comprising a flexible membrane 24. In regard to claim 9, Bobo, Sr. shows a second lumen 22 with a predetermined volume of fluid (column 10, lines 34-36). In regard to claim 10, Bobo, Sr. shows a second lumen 22 free of voids (Figure 6b). In regard to claim 21, Bobo, Sr. shows a sleeve-like pressure sensitive component 24 formed around the distal end of the catheter in fluid communication with the second lumen (Figure 6b). In regard to claim 22, Bobo, Sr. shows a pressure monitoring catheter having an elongate catheter 12d, first lumen 50, second lumen 22 which is separate and fluid-filled, second lumen extending between a pressure-sensitive component 26, and a pressure sensor 14. In regard to claim 23, Bobo, Sr. shows a pressure sensor 14 coupled to the proximal end of the second lumen 22. In regard to claim 28, Bobo, Sr. shows the flexible sleeve (membrane) 24 formed around the distal end of the catheter in fluid communication with the second lumen 22.

9. Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bobo, Sr. Figures 4a-4b. In regard to claim 29, Bobo, Sr. shows a method for measuring intra-ventricular pressure comprising providing a ventricular catheter 12c having a first lumen 22a, a second lumen 22b extending between a distal pressure sensitive member 24, and a proximal pressure sensor 14a (column 13, lines 25-62); implanting the ventricular catheter 12c in such that the pressure sensitive member 24 is

disposed within the ventricle and the pressure sensor 14 is disposed at a location outside of the ventricle (column 15, lines 9-17); an obtaining a pressure reading (column 15, lines 33-57). In regard to claim 30, Bobo, Sr. shows the pressure sensitive member 24 comprises a flexible membrane 64 that is formed across a discontinuity 66 formed in the sidewall of the catheter.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bobo, Sr. (5573007). Bobo, Sr. shows a pressure monitoring catheter as set forth above (Fig. 6b). In another embodiment, Bobo, Sr. teaches the flexible membrane 42a disposed across an opening 82 formed in the sidewall (Fig. 7a) for fluid entry. Therefore it would be obvious for one having ordinary skill in the art at the time of the invention to modify Bobo, Sr. to obtain the invention as specified in claim 6 because such a modification would provide an opening in the sidewall for fluid entry.

12. Claim 7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bobo, Sr. in view of Goldstein et al. (5899937). In regard to claims 7 and 25, Bobo, Sr. shows a pressure monitoring catheter as set forth above including a flexible membrane 24 (Figure 6b). Bobo, Sr. lacks disclosure of the compliance of the flexible membrane. Goldstein et al. teaches a pulsatile flow system with a device comprising a membrane

with adjustable compliance capable of duplicating a compliance value of 0.008 cm^3/mmHg, which is the equivalent of 8μL/mmHg (column 10, lines 25-38), instead of a flexible membrane with a compliance in the range of 0.05μL/mmHg to 2μL/mmHg as disclosed by the applicant. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a flexible membrane with a compliance of 8μL/mmHg because Applicant has not disclosed that a membrane with a compliance in the range of 0.05μL/mmHg to 2μL/mmHg provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Goldstein et al.'s membrane and the Applicant's invention, to perform equally well with either the compliance as taught by Goldstein or the claimed membrane compliance of 0.05μL/mmHg to 2μL/mmHg because both would perform the same function of causing a shift in equilibrium, with little force, and transferring the pressure signal to the sensor.

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bobo, Sr. in view of Fiddian-Green (5174290). Bobo, Sr. shows a pressure monitoring catheter as set forth above including a flexible membrane 24 (Fig. 6b). Bobo, Sr. lacks disclosure of the material composition of the flexible membrane. Fiddian-Green teaches a tonometric catheter with first and second lumen, 22 and 28, and a flexible membrane 36 comprised of polydimethylsiloxane located at the distal tip for the purpose of providing an elastic material responsive to pressure changes (column 5, lines 17-34). It would have been obvious to one having ordinary skill in the art at the time of the invention to have

modified Bobo, Sr. with a flexible membrane composed of a silicone for the purpose of providing a flexible pressure sensitive medium.

14. Claims 11-13, 16-20, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bobo, Sr. in view of Brockway et al. (4846191). In regard to claim 11, Bobo, Sr. shows a pressure monitoring catheter as above. Bobo Sr. lacks disclosure of the volume of the liquid contained in the lumen. Brockway et al. teaches a fluid-filled lumen capable of holding 3μL of fluid based on the dimensions of the lumen disclosed, which is in the range of 1μL to 10μL as claimed by the Applicant. In regard to claims 12 and 26, Bobo, Sr. shows a pressure monitoring catheter as set forth above, second lumen 22 which is separate and fluid-filled, second lumen extending between a pressure-sensitive component 26 comprising a flexible membrane 24. Bobo, Sr. lacks disclosure of the fluid contained in the lumen and its material properties. Brockway et al. teaches a device for measuring body pressure comprising a catheter 10 with a lumen 28 filled with a low viscosity silicone gel fluid 30 (column 5, lines 47-50). In regard to claim 13, Brockway teaches the use of a biocompatible low-viscosity silicone gel fluid within the lumen of the catheter (column 6, lines 1-10). In regard to claim 16, Bobo, Sr. lacks disclosure of the dimensions of the lumens. Brockway et al. teaches a device for measuring body pressure comprising a catheter 10 with a lumen 28 filled with a low viscosity silicone gel fluid 30 (column 5, lines 47-50). Brockway further discloses the fluid-filled lumen 28 has an inside diameter of 0.3 to 0.7 mm and a length of 5 to 25 cm, with both dimension being adjustable depending on the test subject involved. In regard to claim 17, Bobo, Sr. shows a pressure monitoring catheter including a pressure-

sensitive component 26 and a pressure sensor 14. Bobo Sr. lacks disclosure regarding the compliance of the catheter and the pressure-sensitive component. Brockaway et al teaches a pressure transmission catheter with a catheter 120 having compliance less than the pressure sensitive component 130 (column 4 line 65 to column 5 line 65). In regard to claim 18, Brockaway et al. teaches a pressure transmission catheter comprised of a hollow tube made of low compliance material 120. In regard to claims 19 and 27, Bobo, Sr. shows a pressure monitoring catheter as set forth above including a pressure sensor 14. Bobo, Sr. lacks disclosure of the frequency response of the pressure sensor. Brockway et al. teaches a device for measuring body pressure comprising a catheter 10 with a lumen 28 and a pressure sensor 16 that provides a dynamic response of 70Hz, which is greater than 20 Hz as cited in claims 19 and 27. In regard to claim 20, Bobo, Sr. shows a pressure monitoring sensor as set forth above including a pressure sensor 14. Bobo Sr. lacks disclosure of the material properties of the sensor. Brockaway et al. teaches a pressure transmission catheter comprising a pressure transducer assembly 173 with a pressure sensor 174, which is a silicone sensor, in a housing 148. It is known that silicone is a relatively stiff material with low compliance that can range from 0.1μL/mmHg to 0.02μL/mmHg and is appropriate for optimizing the frequency response of the sensor. Therefore it would be obvious for one having ordinary skill in the art at the time of the invention to modify Bobo Sr. with a fluid-filled lumen containing 1μL to 10μL of low viscosity biocompatible fluid; a fluid-filled lumen with a diameter in the range of 0.1mm to 0.3mm and a length of 8cm to 20cm; a low compliance catheter having compliance less than that of the pressure sensitive

component; a pressure senor that has a frequency response of greater than 20Hz; and a sensor that is comprised of silicone as taught by Brockaway et al. since such modifications would optimize the performance of the pressure sensor.

15. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bobo, Sr. in view of Sgourakes (4638656). Bobo, Sr. shows a pressure monitoring catheter as set forth above including a second lumen extending between a pressure-sensitive component 26 comprising a flexible membrane 24. Bobo, Sr. lacks disclosure of the viscosity of the fluid contained in the lumen. Sgourakes teaches a differential pressure transmitter 20 comprising a first and second lumen, 22 and 24, fluid-filled region 50, and flexible membranes 42 and 44. The viscosity of the fill-liquid in the fluid filled region 50 is 5 cs (column 4, lines 400-45) for the purpose of pressure detection. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Bobo Sr. with a fill-liquid having a viscosity of 5 cs as taught by Sgourakes since such modification would provide an accurate measure of pressure.

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bobo, Sr. in view of Wallace et al (5951497). Bobo, Sr. shows pressure monitoring catheter having an elongate catheter 12d, first lumen 50, second lumen 22. Bobo, Sr. lacks teaching a first and second lumen where the second lumen is smaller in diameter. Wallace et al. teaches a pressure catheter device with a second lumen 32 having a smaller diameter than the first lumen 16 for the purpose of providing a space between the first and second lumen for fluid infusion (column 4, lines 19-25). Therefore it would have been obvious for one having ordinary skill in the art at the time of the invention to

modify Bobo, Sr. with a second lumen having a smaller diameter than that of the first lumen as taught by Wallace et al. for the purpose of providing a passage between the first and second lumen.

17. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bobo, Sr. (5573007). Bobo, Sr. shows a pressure monitoring catheter as set forth above (Fig. 6b). In another embodiment, Bobo, Sr. teaches the flexible membrane 42a disposed across a discontinuity 82 formed in the sidewall (Fig. 7a) for fluid entry. Therefore it would be obvious for one having ordinary skill in the art at the time of the invention to modify Bobo, Sr. to obtain the invention as specified in claim 24 because such a modification would provide a flexible membrane covering the discontinuity in the sidewall for fluid entry.

18. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bobo, Sr. (Figures 4a-4b) in view of Goldstein et al. (5899937). Bobo, Sr. shows a pressure monitoring catheter as set forth above including a flexible membrane 24. Bobo, Sr. lacks disclosure of the compliance of the flexible membrane. Goldstein et al. teaches a pulsatile flow system with a device comprising a membrane with adjustable compliance capable of duplicating a compliance value of 0.008 cm^3/mmHg, which is the equivalent of 8μL/mmHg (column 10, lines 25-38), instead of a flexible membrane with a compliance in the range of 0.05μL/mmHg to 2μL/mmHg as disclosed by the applicant. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a flexible membrane with a compliance of 8μL/mmHg because Applicant has not disclosed that a membrane with a

compliance in the range of 0.05μL/mmHg to 2μL/mmHg provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Goldstein et al.'s membrane and the Applicant's invention, to perform equally well with either the compliance as taught by Goldstein or the claimed membrane compliance of 0.05μL/mmHg to 2μL/mmHg because both would perform the same function of causing a shift in equilibrium, with little force, and transferring the pressure signal to the sensor.

19. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bobo, Sr. (Figures 4a-4b) in view of Brockway et al. (4846191). Bobo, Sr. shows a pressure monitoring catheter as set forth above including a second lumen extending between a pressure-sensitive component 26 comprising a flexible membrane 24 and a pressure sensor 14. Bobo, Sr. lacks disclosure of the fluid contained in the lumen and its material properties and the frequency response of the pressure sensor. In regard to claim 32, Brockway et al. teaches a device for measuring body pressure comprising a catheter 10 with a lumen 28 filled with a low viscosity silicone gel fluid 30 (column 5, lines 47-50). In regard to claim 33, Brockway et al. teaches a device for measuring body pressure comprising a catheter 10 with a lumen 28 and a pressure sensor 16 that provides a dynamic response of 70Hz, which is greater than 20Hz as cited in the claimed invention. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Bobo, Sr. with a lumen filled with a low viscosity silicone fluid and a pressure senor that has a frequency response of greater than 20Hz as taught by Brockway et al. since such modification would provide a low viscosity fluid

within the lumen of the catheter and a pressure sensor that could detect sensitive pressure changes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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